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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,501	08/09/2000	Susan Acton	MNI-132CP3	5106

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INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICAL, INC.
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EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,501	ACTON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) 8-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 17, 44 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This Office Action is in response to Paper No. 6, filed 03 September 2002, wherein Applicants elected Group II, claims 2-7 and 17 with traverse, canceled claims 1 and 18-43 without prejudice, amended claims 5-8 and 17, and added new claims 44-48.

Applicant's election with traverse of Group II, claims 2-7 and 17 in Paper No. 6, filed 03 September 2002, is acknowledged. The traversal is on the ground(s) that Groups II and III are both directed to polypeptides. Applicants also state the polypeptides of Group III are variants or fragments of the polypeptide of Group II. This is not found persuasive because the isolated polypeptide of claim 8 in Group III is limited by claim 16 in Group III as being "encoded by a nucleic acid which hybridizes to a nucleic acid having the nucleotide sequence set forth in SEQ ID NO: 1 or compliment thereof." It is noted by the examiner that as claimed in claim 6 of Group II that the isolated polypeptide of Group II is encoded by the nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO: 1, and therefore, the polypeptide of Group III that is encoded by a nucleotide sequence that hybridizes to the nucleotide sequence of SEQ ID NO: 1 is a different and distinct polypeptide than that encoded by SEQ ID NO: 1.

The requirement is still deemed proper and is therefore made FINAL.

Objections

The disclosure is objected to because of the following informality. The address of the American Type Culture Collection found on page 13 of the specification is incorrect, as the ATCC has relocated. The present address is 10801 University Blvd., Manassas, VA 20110-2209. Amendment of the disclosure to indicate the current address is required.

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Claims are objected to because they lack proper introduction. The present Office practice is to insist that each claim be the object of a sentence starting with a phrase such as "I (or we) claim" or "What is claimed is" or "That which is claimed is". See MPEP 608.01 (m). Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e. "allelic variants of a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features

common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* SEQ ID NO: 2. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises all allelic variants of a polypeptide. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 2, 17, 44 and 46-48 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 17, 44 and 47 are rejected for the recitation of the indefinite term “at least about”, wherein it is unclear whether the claimed sequence identity is at least 70% or about 70%, and whether the claimed number of consecutive amino acid residues is at least 50 or about 50. The term about can be less than 70% or less than 50 consecutive amino acid residues, however, at least 70% and at least 50 consecutive amino acids means 70% or more and 50 or more. The Applicants should delete the word “about” from the claims.

Claim 2 is indefinite for use of the phrase “having an amino acid identity of at least about 70%”. It is unclear as to what identity means in this phraseology. The claim would be clearer if amended to read: “An isolated polypeptide comprising an amino acid sequence of at least 70% sequence identity with the entire amino acid sequence set forth in SEQ ID NO: 2.” Sequence identity or sequence similarity is recognized terminology for claiming sequence inventions.

Claims 3-4 are rejected for depending from rejected claim 2.

Claims 17 and 47 are rejected for the recitation of the indefinite term “a bioactivity of an ACE-2 polypeptide.” “A” in this phrase can mean any one of many bioactivities of an ACE-2 polypeptide and it is unclear which one bioactivity was intended or if all bioactivities were encompassed by these claims. Claims 17 and 47 are rejected for the acronym “ACE” wherein the represented words should be spelled out in entirety the first time followed by the acronym in parentheses, and the acronym used thereafter.

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Claim 46 is rejected for the indefinite recitation of the phrase "allelic variant of a polypeptide." Applicants should amend the claim to specify what polypeptide has the allelic variant, i.e. ACE polypeptide.

Claim 48 is rejected for being drawn to non-elected subject matter.

Conclusion

5. Claims 1 and 18-43 canceled. Claims 2-17 and 44-48 pending, of which, claims 8-16 are withdrawn from consideration. Claims 2-7, 17 and 44-48 were examined on merits, with claims 2-4, 17, 44 and 46-48 rejected. Claims 5-7 and 45 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
02 December 2002


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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